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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,155	PREDAL, LUDOVIC	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14 and 17-19* is/are pending in the application.

4a) Of the above claim(s) *17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on April 23, 2008 have been received and entered into the case. Claims 2, 15 and 16 are canceled; claims 17 – 19 are added; claims 1, 3 – 14 and 17 - 19 are pending; claims 17 - 19 are withdrawn; claims 1 and 3 - 13 have been considered on the merits. All arguments have been fully considered.

Election/Restrictions

Newly submitted claims 17 – 19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a method which is distinct from the neutraceutical claims originally presented. Specifically, the composition can be used in other materially different methods such as those disclosed by the references of record.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17 – 19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

1. Claim 1 is objected to because of the following informalities:

In claim 1, line 2, "compositions" should read "composition".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2 – 14 and rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are confusing for reciting "global" because it is unclear what applicant intends to encompass by this term.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 2, 4 – 8, 10 – 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Nippon Oils (JP 03297364).

Nippon Oils teaches a pharmaceutical powder comprising at least 10% EPA and DHA; and 20 – 70% ALA, wherein the fats are oils derived from sardines and Perilla species (abstract).

The reference anticipates the claimed subject matter.

6. Claims 1 – 2, 4 – 5, 8, 10 – 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeo (US 5312834).

Yeo teaches a pharmaceutical composition comprising EPA and ALA which are derived from fish and perilla oils (abstract). Specifically, the EPA is present at 5 – 30% and the perilla oil containing ALA is present at 40 – 70% (col.4 line 5-15) and the composition is a capsule (col.4 line 49-51) or liquid (one spoonful, col.4 line 60-66).

Although the reference does not teach including DHA, the claims as written do not require DHA, but is listed as an alternative to EPA. Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 9 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon in view of Maingault (FR 2721517).

Nippon Oils teaches a pharmaceutical powder comprising at least 10% EPA and DHA; and 20 – 70% ALA, wherein the fats are oils derived from sardines and Perilla species (abstract).

Nippon does not teach the composition wherein the ALA is derived from kiwi seed oil. However, at the time of the claimed invention, kiwi seed oil was known to be a rich source of ALA. In support, Maingault teaches that kiwi seeds are high in ALA and that administration of the oil is suitable for pharmaceutical administration. At the time of the claimed invention, it would have been obvious to use kiwi seed oil as the source of ALA in the composition of Nippon since it was a known source of ALA, as evidenced by Maingault. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Maingault to use kiwi seed oil in the composition of Nippon with a reasonable expectation for successfully obtaining the effective pharmaceutical on Nippon.

Nippon does not teach the composition wherein the ALA is in the claimed form or wherein one of the claimed carriers is present. However, at the time of the claimed invention, the claimed forms and carriers were well known and used in the art for their claimed purpose as a matter of routine practice. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to use any of the forms of ALA or claimed carriers in the composition of Nippon with a reasonable expectation for successfully obtaining the effective composition of Nippon.

Nippon does not teach the claimed amounts of ALA, EPA and DHA. However, each of the claimed components are noted as active ingredients by Nippon. Thus, the amounts of these

components are recognized result effective variables. Moreover, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of fatty acids with a reasonable expectation for successfully obtaining an effective pharmaceutical composition.

9. Claims 3, 6 – 7, 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeo in view of Maingault.

Yeo teaches a pharmaceutical composition comprising EPA and ALA which are derived from fish and perilla oils (abstract). Specifically, the EPA is present at 5 – 40% and the perilla oil containing ALA is present at 40 – 70% (col.4) and the composition is a capsule (col.4 line 49-51) or liquid (one spoonful, col.4 line 60-66). Although the reference does not teach including DHA, the claims as written do not require DHA, but is listed as an alternative to EPA.

Yeo does not teach the composition wherein the EPA is derived from the claimed fish or ALA is derived from kiwi seed oil. However, Yeo teaches that commercially available fish are suitable for providing the source of fish oil (col.4). At the time of the claimed invention, each of the claimed fish were known, commercially available fish. IN addition, kiwi seed oil was known to be a rich source of ALA. In support, Maingault teaches that kiwi seeds are high in ALA and that administration of the oil is suitable for pharmaceutical administration. At the time of the claimed invention, it would have been obvious to use the claimed fish and kiwi seed oils as the source of EPA and ALA in the composition of Yeo since Yeo suggests commercially available fish, and kiwi seed were a known source of ALA, as evidenced by Maingault. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by

common knowledge and the teachings of Maingault to use the instant sources of oils in the composition of Yeo with a reasonable expectation for successfully obtaining the effective pharmaceutical on Yeo.

Yeo does not teach the composition wherein the ALA is in the claimed form or wherein one of the claimed carriers is present. However, at the time of the claimed invention, the claimed forms and carriers were well known and used in the art for their claimed purpose as a matter of routine practice. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to use any of the forms of ALA or claimed carriers in the composition of Yeo with a reasonable expectation for successfully obtaining the effective composition of Yeo.

10. Claims 1 – 8 and 10 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura et al. (US 5756088).

Matsuura teaches nutriceutical compositions comprising GLA, ALA, EPA and DHA (abstract, col.2 line 5-10) wherein the GLA and ALA are derived from plant oils and the EPA and DHA are derived from fish oils to include sardines and tuna (col.2 line 10-20). The fatty acids are present at 1 – 50% (col.2 line 55-60) and the composition may be a powder, granule or solution (liquid) (col.3 line 30-35).

Matsuura does not teach the composition wherein the claimed carriers are present. However, at the time of the claimed invention, the claimed carriers were well known and used in the art for their claimed purpose as a matter of routine practice. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice

to use any of the claimed carriers in the composition of Matsurra with a reasonable expectation for successfully obtaining the effective composition of Matsuura.

Matsuura does not teach the claimed amounts of fatty acids. However, each of the claimed components are noted as active ingredients by Matsuura. Thus, the amounts of these components are recognized result effective variables. Moreover, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of fatty acids with a reasonable expectation for successfully obtaining the effective composition of Matsuura.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura in view of Maingault.

Matsuura teaches nutriceutical compositions comprising GLA, ALA, EPA and DHA (abstract, col.2 line 5-10) wherein the GLA and ALA are derived from plant oils (col.2 line 10-20). The fatty acids are present at 1 – 50% (col.2 line 55-60) and the composition may be a powder, granule or solution (liquid) (col.3 line 30-35).

Matsuura does not teach the claimed amounts of fatty acids. However, each of the claimed components are noted as active ingredients by Matsuura. Thus, the amounts of these components are recognized result effective variables. Moreover, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of fatty acids with a reasonable expectation for successfully obtaining the effective composition of Matsuura.

Matsuura does not teach the composition wherein the ALA is derived from kiwi seed oil. However, at the time of the claimed invention, kiwi seed oil was known to be a rich source of ALA. In support, Maingault teaches that kiwi seeds are high in ALA and that administration of the oil is suitable for pharmaceutical administration. At the time of the claimed invention, it would have been obvious to use kiwi seed oil as the source of ALA in the composition of Matsurra since it was a known source of ALA, as evidenced by Maingault. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Maingault to use kiwi seed oil in the composition of Matsurra with a reasonable expectation for successfully obtaining the effective pharmaceutical on Matsuura.

Response to Arguments

Applicant argues that the references teach compositions with additional components that are included and are biologically active, different uses for the compositions, and different dosages.

However, these arguments fail to persuade because the claims are drawn to a composition that may comprise the instantly claimed components which fails to exclude additional components. In addition, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that

when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). Finally, regarding the dosages, it is noted that all of the claims do not require a particular dosage amount. Moreover, the argument is not commensurate in scope with all of the claimed compositions.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651

August 3, 2008.